

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number: k043474

B. Purpose For Submission:

Premarket Notification 510(k) of intention to manufacture and market the Roche Diagnostics Corp. ACCU-CHEK Aviva System.

C. Analyte: Whole Blood Glucose

D. Type of Test: Quantitative, utilizing Glucose dehydrogenase technology.

E. Applicant: Roche Diagnostics

F. Proprietary and Established Names: ACCU-CHEK® Aviva System.

G. Regulatory Information:

1. Regulation section: 21 CFR §862.1345, Glucose test system.
21 CFR §862.1660, Quality control material (assayed and unassayed).
2. Classification: Class II, Class I (reserved)
3. Product Code: NBW, LFR, JJX
4. Panel: 75 Chemistry

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

The ACCU-CHEK® Aviva system is designed to quantitatively measure the concentration of glucose in capillary whole blood by persons with diabetes or by health care professionals for monitoring blood glucose in the home or health care facility. The device is indicated for professional use and over-the-counter sale. Professionals may use the test strips to test capillary and venous blood samples; lay use is limited to capillary whole blood testing. Testing sites include traditional fingertip site along with palm, forearm, upper arm, thigh, and calf.

3. Special condition for use statement(s):

Provides plasma equivalent results.

4. Special instrument Requirements:

Roche Diagnostics Corp. ACCU-CHEK® Aviva System

I. Device Description:

The ACCU-CHEK Aviva system utilizes reagent test strips stored within a desiccated vial. A test strip is removed from the vial and inserted into the meter. Upon insertion, the meter is activated. Blood is applied to the end of the test strip and a glucose result is reported.

The ACCU-CHEK Aviva system includes:

- ACCU-CHEK Aviva meter with battery
- ACCU-CHEK test strips and code key (may be sold separately)
- ACCU-CHEK Aviva control solutions (may be sold separately)
- ACCU-CHEK Softclix lancet device (with blue cap for fingertip testing and a clear cap for non-fingertip testing)
- ACCU-CHEK Softclix lancets

J. Substantial Equivalence Information:1. Predicate device name(s):

Roche Diagnostics, Corp. ACCU-CHEK Advantage System

2. Predicate K number(s): K010362 and K0325523. Comparison with Predicate:

The sponsor claims that the Roche Diagnostics ACCU-CHEK Aviva system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Roche Diagnostics ACCU-CHEK Advantage system.

Similarities

Topic	Comment
Intended Use	Both systems are intended for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities.
Closed system	Each system's test strips and controls are designated to be used only with that

	system.
Sample types	Both systems utilize whole blood samples (capillary or venous).
Home and Professional use	Both systems are intended to be used by persons in their home, or by health care professionals in health care facilities
Test strip storage conditions	Store at room temperature, less than 90° F. Do not freeze.
Quality control procedure	Quality controls are tested when the cap is left off the vial of test strips, when a new vial is opened, if the meter is dropped, if the result does not agree with the way the user feels, whenever the user wishes to check to performance of the system.
Reportable range	10 – 600 mg/dL
Warnings and precautions	Both systems are for in vitro diagnostic use only.
Monitor coding process	Both systems use a code key, included in the test strip vial, inserted into the meter.
Test strip packaging	Both systems provide test strips in a desiccated vial.

Differences

Topic	ACCU-CHEK Aviva	ACCU-CHEK Advantage
Indication of control solution results	Automatically distinguishes control solution from whole blood samples.	User must identify (flag) the control solution result manually.
Test sample volume	0.6 µL	4.0 µL
Test time	5 seconds	26 seconds (Comfort Curve test strips)
Expiration	In addition to information included in labeling, the code key contains expiration date of associated test strips. System informs user when code key has expired.	No notification of expiration beyond that included in labeling.
Test strip technology	The system utilizes both AC/DC electrical impedance information.	The system utilizes electrical biamprometry information.
Labeling instructions regarding expected results	The normal fasting blood glucose range for an adult without diabetes is 74-106 mg/dL. Two hours after meals, the blood glucose range for an adult without	The normal fasting adult blood glucose range for a non-diabetic is 70-105 mg/dL. One to tow hours after meals, normal blood glucose levels should be

	diabetes is less than 140 mg/dL. For people with diabetes: please consult your doctor for the blood glucose range appropriate for you.	less than 140 mg/dL. Doctors will determine the range that is appropriate for their individual patients.
--	--	--

K. Standard/Guidance Document Referenced (if applicable):

NCCLS EP6-A standard, "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach."

ISO 15197 standard minimum acceptable accuracy acceptance criteria (within ± 15 mg/dL for <75 mg/dL and within $\pm 20\%$ for ≥ 75 mg/dL)

QA 43-SOP Procedure for Establishing the Precision Claim of Blood Glucose Systems.

L. Test Principle:

The ACCU-CHEK Aviva System utilizes Glucose dehydrogenase technology. The enzyme glucose dehydrogenase converts the glucose in a blood sample to gluconolactone. This reaction liberates an electron that reacts with a coenzyme electron acceptor, the oxidized form of the mediator hexacyanoferrate (III), forming the reduced form of the mediator hexacyanoferrate (II). The test strip employs the electrochemical principle of biamprometry. The meter applies a voltage between two identical electrodes, which causes the reduced mediator formed during the incubation period to be reconverted to an oxidized mediator. This generates a small current that is read by the meter and reported as the glucose result.

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

The sponsor indicated precision studies were assessed by taking venous blood samples that were treated with EDTA, and spiking these samples to generate 5 different levels of glucose concentration for the test. Each of the samples was measured 10 times. Below are the Glucose Concentration Ranges and results for each level that was measured.

Blood	Level 1 30-50 mg/dL	Level 2 51-110 mg/dL	Level 3 111-150 mg/dL	Level 4 151-250 mg/dL	Level 5 251-400 mg/dL
N	10	10	10	10	10
Mean	38	107	143	245	341
SD	1.6	3.0	3.7	4.9	7.5
CV	4.21	2.8	2.6	2.0	2.2

Day-to-Day precision also known as Between Day Precision

The Day-to-Day precision according to the sponsor was determined by preparing three control and blood solutions of Low, Normal and High. The sponsor indicated that the protocol used for this comparison was based on requirements outlined in QA 43-SOP Procedure for Establishing the Precision Claim of Blood Glucose Systems. As an outcome of this study, the following precision claim is included in the labeling of the product:

Control Solution	Low (mg/dL)	Mid (mg/dL)	High (mg/dL)
N	10	10	10
Mean	41	130	306
SD	1.1	2.4	5.0
CV	2.68	1.8	1.5

Blood	Low (mg/dL)	Mid (mg/dL)	High (mg/dL)
N	10	10	10
Mean	38	143	341
SD	1.6	3.7	7.5
CV	4.21	2.6	2.2

b. Linearity/assay reportable range:

The linearity was established by diluting specimens to cover the range of 3- 677 mg/dL.

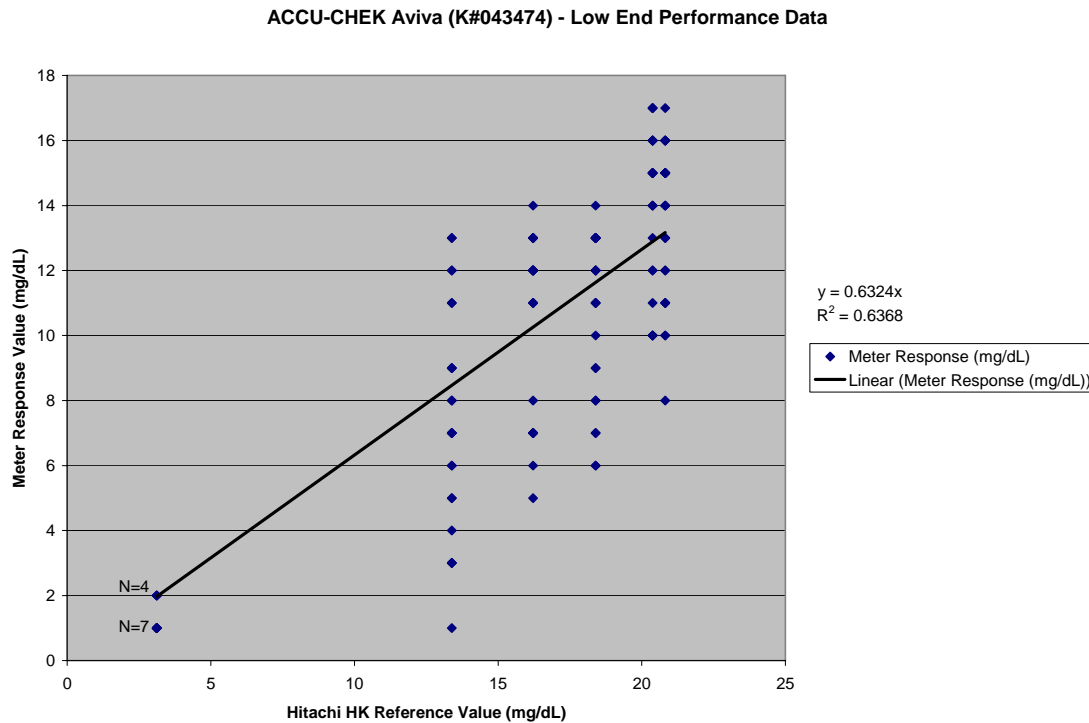
For linearity, the sponsor chose to use the ISO 15197 Standard minimum acceptable accuracy acceptance criteria (within ± 15 mg/dL for glucose results < 75 mg/dL, and within $\pm 20\%$ for glucose results ≥ 75 mg/dL) see low end data below.

Test Strip Lot	Hitachi HK Reference Value (mg/dL)	Meter Response (mg/dL)	Consumer would see
74	3.1	1	LO
74	3.1	1	LO
72	3.1	1	LO
72	3.1	1	LO
72	3.1	1	LO
72	3.1	1	LO
73	3.1	1	LO
73	3.1	1	LO
74	3.1	2	LO
74	3.1	2	LO
73	3.1	2	LO
73	3.1	2	LO

Test Strip Lot	Hitachi HK Reference Value (mg/dL)	Meter Response (mg/dL)	Consumer would see
72	13.4	1	LO
72	13.4	3	LO
72	13.4	3	LO
72	13.4	3	LO
72	13.4	4	LO
72	13.4	5	LO
72	13.4	5	LO
72	16.2	5	LO
72	13.4	6	LO
72	16.2	6	LO
72	18.4	6	LO
72	18.4	6	LO
72	16.2	7	LO
72	16.2	7	LO
72	16.2	7	LO
72	16.2	7	LO
72	16.2	7	LO
72	18.4	7	LO
72	18.4	7	LO
72	16.2	8	LO
72	18.4	8	LO
72	18.4	8	LO
72	20.8	8	LO
72	18.4	9	LO
72	18.4	9	LO
72	20.4	10	10
72	20.4	10	10
72	20.4	10	10
72	20.4	10	10
72	20.8	10	10
72	20.8	10	10
72	20.4	11	11
72	20.8	11	11
72	20.8	11	11
72	20.8	11	11
72	20.4	12	12
72	20.4	12	12
72	20.8	12	12
72	20.8	12	12
72	20.4	13	13
73	13.4	7	LO
73	13.4	7	LO
73	13.4	7	LO
73	13.4	9	LO

Test Strip Lot	Hitachi HK Reference Value (mg/dL)	Meter Response (mg/dL)	Consumer would see
73	18.4	10	10
73	13.4	11	11
73	16.2	11	11
73	16.2	11	11
73	16.2	11	11
73	18.4	11	11
73	18.4	11	11
73	18.4	11	11
73	13.4	12	12
73	13.4	12	12
73	16.2	12	12
73	16.2	12	12
73	16.2	12	12
73	18.4	12	12
73	18.4	12	12
73	13.4	13	13
73	16.2	13	13
73	16.2	13	13
73	18.4	13	13
73	18.4	13	13
73	20.8	13	13
73	20.8	13	13
73	20.4	14	14
73	20.4	14	14
73	20.8	14	14
73	20.8	14	14
73	20.4	15	15
73	20.4	15	15
73	20.8	15	15
73	20.8	15	15
73	20.8	15	15
73	20.4	16	16
73	20.4	16	16
73	20.8	16	16
73	20.4	17	17
73	20.4	17	17
74	13.4	6	LO
74	13.4	7	LO
74	13.4	8	LO
74	13.4	8	LO
74	13.4	9	LO
74	13.4	9	LO
74	13.4	11	11
74	16.2	12	12

Test Strip Lot	Hitachi HK Reference Value (mg/dL)	Meter Response (mg/dL)	Consumer would see
74	16.2	12	12
74	16.2	12	12
74	16.2	12	12
74	18.4	12	12
74	18.4	12	12
74	13.4	13	13
74	16.2	13	13
74	16.2	13	13
74	16.2	13	13
74	18.4	13	13
74	18.4	13	13
74	18.4	13	13
74	18.4	13	13
74	18.4	13	13
74	16.2	14	14
74	18.4	14	14
74	20.4	14	14
74	20.8	14	14
74	20.4	15	15
74	20.4	15	15
74	20.4	15	15
74	20.8	15	15
74	20.8	15	15
74	20.8	15	15
74	20.4	16	16
74	20.4	16	16
74	20.4	16	16
74	20.8	16	16
74	20.8	16	16
74	20.8	16	16
74	20.4	17	17
74	20.8	17	17
count	132	132	
mean	16.5	10	
min	3.12	1	
max	20.8	17	



c. Traceability (controls, calibrators, or method):

During the control solution production process, anhydrous glucose material is weighed out to within 0.2% of the target weight. Prior to bottling the final product a sample of the solution is verified via a Hitachi hexokinase method.

d. Detection limit:

See linearity above
 10 – 600 mg/dL
 0.6 to 33.3 mmol/L

e. Analytical specificity:

According the sponsor interference testing was conducted to determine the effect of select endogenous and exogenous substances. Testing was conducted using a glucose depleted normal human serum matrix spiked with the potential interferents at the acceptable upper concentrations. The recommended test level was based the on EP7-A NCCLS guidelines and literature references. This study included a total of 177 compounds which were screened, of which the following will be claimed as limitation:

- Galactose
- Lipidemia (Triglycerides)

- Maltose
- Xylose (Xylose will not be tested in whole blood but will be listed as a limitation based on serum results.

The below compounds when determined to be in excess of their limitations, may produce elevated results:

1. Galactose > 10 mg/dL can give falsely elevated test results.
2. Maltose > 13 mg/dL delivered intravenously can give falsely elevated test results.
3. Lipids (Triglycerides) > 4800 mg/dL can give falsely elevated test results

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

A consumer blood study comparisons, to the Reference Method was conducted, where capillary blood sample results obtained by untrained patients from three physician offices gave the following results.

$N = 97$

$Y = 0.957x + 2.7$

$R = 0.982$

Range = 73 – 330 mg/dL

b. Matrix comparison:

Studies for matrix comparison were conducted at one physician site for capillary blood samples and three physician office sites for venous blood samples with the following results:

Capillary Blood

$N = 212$

$Y = 0.984x + 2.2$

$R = 0.996$

Range = 26 – 461 mg/dL

Venous Blood

$N = 227$

$Y = 0.993x + 0.3$

$R = 0.994$

Range = 32 – 583 mg/dL

Alternate Site Testing

The sponsor demonstrated Alternate Site Testing (AST) of the palm, forearm, upper arm, thigh, and calf with the clearance of 510(k) submission K022171 Roche Diagnostics ACCU-CHEK Compact System. The sponsor has AST studies on two (2) sites with the new device, comparing to the fingertip as the reference method in this submission.

In the AST accuracy study performed by the sponsor, a trained technician performed a minimum of four capillary sticks on each patient to include a capillary fingerstick as a reference, capillary forearm stick, capillary palm thenar (thumb side) and a second capillary fingerstick used and hematocrit sample. As indicated in the above previously cleared submission K022171, the sponsor has included label warnings not recommending AST testing during periods of rapidly decreasing or increasing blood glucose levels.

The percentage of individual results falling outside 15 mg/dL for glucose results < 75 mg/dL and 20% for glucose results \geq 75 mg/dL was 3.2% for the pooled data, which was not significantly higher than the 5% acceptance criteria. The Hematocrit range obtained was 23-51% with a mean of 40.5%.

3. Clinical studies:

- a. *Clinical sensitivity:*
Not Applicable
- b. *Clinical specificity:*
Not Applicable
- c. *Other clinical supportive data (when a and b are not applicable):*
Not Applicable

4. Clinical cut-off: Not Applicable

5. Expected values/Reference range:

The normal fasting blood glucose range for an adult without diabetes as related to plasma is 74-106 mg/dL¹. Two hours after meals, blood glucose range for a non-diabetic is less than 140 mg/dL². For people with diabetes please consult your diabetes team for the blood glucose range appropriate for you.

- 1. Stedman, TL, Stedman's Medical Dictionary, 27th Edition, 1999, pg. 2082.
- 2. American Diabetes Association, Clinical Practice Recommendation Guidelines 2003, Diabetes Care, Vol. 26. Supplement 1, p. S22.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

O. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.